

Amendment and Response

Page 14 of 19

Serial No.: 10/728,577

Confirmation No.: 8901

Filed: 5 December 2003

For: POLYMER COMPOSITIONS WITH BIOACTIVE AGENT, MEDICAL ARTICLES, AND METHODS**Remarks**

The Office Action mailed May 27, 2008 has been received and reviewed. Claims 2, 4, 6, 7, 9, 11, 13, 15, 17-22, 60, 75, and 76 having been amended, claims 1, 27-59, 61-74 having been cancelled, without prejudice, and claims 77-121 having been added, the pending claims are claims 2-26, 60, and 75-121. Reconsideration and withdrawal of the rejections are respectfully requested.

Support for the new and amended claims can be found throughout the application. For example, each independent claim (77, 79, 82, and 85) recites "a continuous hydrophobic liquid phase and absorbent hydrophilic polymer microparticles dispersed within the hydrophobic liquid phase." This is supported by the specification at, for example, page 7, lines 7-9. Each of independent claims 77 and 82 recite that the microparticles comprise a poly(quaternary amine)-containing organic polymer. This is supported by the specification at, for example, page 4, lines 13-15 and page 6, lines 26-28. Each of independent claims 79 and 85 recite that the microparticles comprise a polylactam-containing organic polymer. This is supported by the specification at, for example, page 4, lines 13-15 and page 6, lines 26-28. Each of the new dependent claims are supported by the originally filed claims.

Information Disclosure Statement

Please disregard our request for consideration of the 1449 listed as Exhibit A in the Response dated February 21, 2008, as this was an error on our part. Applicants acknowledge that all documents cited thereon had been considered previously.

Double Patenting Rejection

Claims 2-26, 60, 71 and 74-76 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12-51, 53-55, 58-93; 1-34; and 1-44 of copending Application Nos. 10/728,439 and 10/728,446. Claims 2-26, 60, 71 and 74-76 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending

Amendment and Response

Page 15 of 19

Serial No.: 10/728,577

Confirmation No.: 8901

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For: POLYMER COMPOSITIONS WITH BIOACTIVE AGENT, MEDICAL ARTICLES, AND METHODS

Application No. 10/729,114 in view of Asmus (U.S. Patent No. 5,270,358). Upon an indication of otherwise allowable subject matter, and in the event these rejections are maintained, an appropriate response will be provided.

The 35 U.S.C. §102/103 Rejection

The Examiner rejected claims 2-17, 20-23, 71, and 74-76 under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over Lorenzi et al. (U.S. Patent No. 6,217,889). Independent claims 71 and 74 having been cancelled, and each of the dependent claims having been amended in their dependency, this rejection is rendered moot.

It is noted that claims 18, 19, 24, 25, and 26 were not included in this rejection.

Accordingly, the subject matter of claims 18 and 26 has been incorporated into independent claims as follows.

The language of claim 18 (wherein the microparticles are present in an amount of 1 wt-% to 60 wt-%, based on the total weight of the polymer composition), which previously depended from claim 71, has been combined with the language of claim 71 and rewritten in independent form as claim 77. It is noted, however, that claim 77 does not include the recitation that the composition is nonadherent, or that the microparticles include a polylactam and/or a polyamide. It is further noted that the language "an inverse emulsion comprising absorbent hydrophilic microparticles" (in previous claim 71) has been replaced by "a continuous hydrophobic liquid phase and absorbent hydrophilic polymer microparticles dispersed within the hydrophobic liquid phase" (in claim 77) to clarify the invention.

Also, the language of claim 26 (wherein the method further comprises combining the components in the presence of water and removing a substantial portion of the water), which previously depended from claim 71, has been combined with the language of claim 71 and rewritten in independent form as claim 82. It is noted, however, that claim 82 does not include the recitation that the composition is nonadherent, or that the microparticles include a polylactam and/or a polyamide. It is further noted that the language "an inverse emulsion comprising absorbent hydrophilic microparticles" (in previous claim 71) has been replaced by "a continuous

Amendment and Response

Page 16 of 19

Serial No.: 10/728,577

Confirmation No.: 8901

Filed: 5 December 2003

For: POLYMER COMPOSITIONS WITH BIOACTIVE AGENT, MEDICAL ARTICLES, AND METHODS

hydrophobic liquid phase and absorbent hydrophilic polymer microparticles dispersed within the hydrophobic liquid phase" (in claim 82) to clarify the invention.

Also, the language of claim 18 is recited in independent claim 79, and the language of claim 26 is recited in independent claim 85.

Applicants request acknowledgement of allowability of claims 77, 79, 82, and 85 (and dependent claims thereon) over Lorenzi et al.

The Examiner rejected claims 2-26, 60, 71, and 74-76 under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over Asmus (U.S. Patent No. 5,270,358). Independent claims 71 and 74 having been cancelled, and each of the dependent claims having been amended in their dependency, this rejection is rendered moot.

Although claim 74 was included within this rejection in the present Office Action, it was not previously rejected under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over Asmus (U.S. Patent No. 5,270,358) in the Office Action dated November 30, 2007 (see paragraph 8, page 5 of that Office Action). Furthermore, the Examiner has not indicated where Asmus discloses that "microparticles comprise a poly(quaternary amine)-containing organic polymer" as recited in present independent claims 77 and 82. It is respectfully submitted that incorporation of claim 74 into this rejection was an error. Applicants request acknowledgement of allowability of claims 77 and 82 (and dependent claims thereon) over Asmus.

With respect to independent claims 79 and 85, which recite that the "microparticles comprise a polylactam-containing organic polymer" and that the polymer composition is nonadherent, Applicants incorporate by reference the previous arguments made with respect to Asmus. Asmus is directed to a gel-adhesive composite, i.e., a dispersed gel in an adhesive matrix. In contrast, Applicants claims are directed to a wound dressing that includes a nonadherent polymer composition. As explained at page 4, lines 3-10 of Applicants' specification, the polymer composition itself is nonadherent (to steel per the test outlined, and preferably to wound tissue), although the nonadherent composition could be used in combination

Amendment and Response

Page 17 of 19

Serial No.: 10/728,577

Confirmation No.: 8901

Filed: 5 December 2003

For: POLYMER COMPOSITIONS WITH BIOACTIVE AGENT, MEDICAL ARTICLES, AND METHODS

with a pressure sensitive adhesive, for example, in an article (e.g., a wound dressing). There is no teaching or suggestion in Asmus (or any motivation provided by any of the other documents cited by the Examiner) to make a nonadherent composition. The gel-adhesive composite adhesive strength in Asmus "at the very least ranges from about 40% to about 500% of the adhesive strength of the adhesive alone" (col. 20, line 12).

The Examiner stated at page 8 of the Office Action that "applicant has not provided a showing that the composition of Asmus adheres to steel or skin or wound." It is respectfully submitted that Asmus has done this. For example, T-Peel Adhesion data is presented in Tables IX, XI, XIII, XIV, XVI, and XVIII. At column 20, lines 5-7, Asmus teach that "the T-Peel adherence to low density polyethylene (LDPE) . . . is used to simulate skin adhesion." Applicants have used stainless steel to simulate skin adhesion. Stainless steel is a standard peel surface and is regularly used for testing pressure sensitive adhesive adhesion (British Pharmacopoeia Appendix XX H, HMSO, London, 1988). A strong correlation between the adhesion to steel plate and adhesion to skin was noted in pressure sensitive adhesive cosmetic patches (H. Mahdavi et al., Indian Journal of Dermatology, Venereology and Leprology, Vol. 72, No. 6, November-December, 2006, pp. 432-436). While no substrate exactly mimics skin, stainless steel has the best ability to distinguish among the medical tapes. Overall, for quality control purposes (yielding good discrimination and precision), stainless steel is the optimal substrate, according to AM Wokovich et al., Biomed Mater Res B Appl Biomater, Published online Apr 3, 2008.

Although some of the values in Tables XVI and XVIII, for example, of Asmus are relatively low, there is at least some adhesion in all the examples in these tables. A peel force of 100 g/cm is equal to 9.8 N/dm. In contrast, Applicants' Example 24, which is representative of Applicants' invention, demonstrated no adhesion (0.0 N/dm) to stainless steel.

It is respectfully submitted that because LDPE has a lower surface energy surface than stainless steel, it is much more difficult to adhere a material to LDPE than to stainless steel (see U.S. Patent Publication No. 2006/251893 A1, Table 1). Thus, if a material (such as the materials

Amendment and Response

Page 18 of 19

Serial No.: 10/728,577

Confirmation No.: 8901

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of Asmus) adheres to LDPE, it is much more likely to adhere to stainless steel and to demonstrate a greater level of adhesion.

Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §102(b), or in the alternative, under 35 U.S.C. §103(a).

Amendment and Response

Page 19 of 19

Serial No.: 10/728,577

Confirmation No.: 8901

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Summary

It is respectfully submitted that the pending claims 2-26, 60, and 75-121 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 21st day of August, 2008, at 11:59 am (Central Time).

By:

Name:

Sara E. Wigan